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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/669,082 | 09/25/2000 | Richard L. Scopp | 6734.US.O1 | 3368 |

23492 7590 08/22/2003

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| EXAMINER | |
|---|---|
| DO, PENSEE T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 08/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/669,082 | SCOPP ET AL. | |
| | Examiner | Art Unit | |
| | Pensee T. Do | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Amendment Entry & Claim Status*

The amendment filed on June 9, 2003 has been acknowledged and entered.

Claims 1-17 are pending.

### *Withdrawn Rejection(s)*

The rejections under 103(a) for claims 17 and 26 are withdrawn herein.

The rejection under 35 USC 112, 2nd paragraph in the previous office action is withdrawn herein.

### *Newgrounds of Rejection(s)*

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 11 recites a MERQUAT compound which is a trademark compound. The use of the trademark MERQUAT has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claims 1, 17 and 26 are missing a critical step because the preamble recites "A method for decreasing interferences which result in inaccurate readings in serum or plasma sample" but the body of the claim fails to recite any step of decreasing the interferences in serum or plasma sample.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petry et al. (US 6,406,858) in view of Cantor (US 5,994,085) and further in view of Diamandis (US 5,688,658).

Petry has been discussed above.

However, Petry fails to teach a method of detecting free prostate specific antigen.

Cantor teaches a method for detecting ***free*** prostate specific antigen (fPSA) comprising pretreating the sample to remove complex PSA and then assaying the fPSA by a sandwich immunoassay using two antibodies. The first antibody is specific for fPSA and is affixed on a solid phase. The second antibody is specific for another epitope site on the fPSA and contains a signal component that can be measured such as a fluorescer, luminescent molecule etc.

It would have been obvious to one of ordinary skills in the art to combine the general teaching of Petry for a method of determining the concentration of an analyte, in which the method requires the step of adding a scavenger conjugate of an enzyme and a water soluble protein or non-proteinaceous natural or synthetic polymer or oligomer to reduce the interaction of unknown interferents which results in an inaccurate readings with the teaching of Cantor in detecting free prostate specific antigen to the advantage of reducing interferents in the serum sample. Furthermore, since Petry suggests detecting analyte such prostate specific antigen, it would have been obvious to one of ordinary skills in the art detect free prostate specific antigen.

However, Cantor fails to teach using acridinium as luminescent label.

Diamandis teaches using chemiluminescent labels such as acridinium esters in immunoassay to detect prostate specific antigen (PSA). (see col. 5, lines 17-24).

It would have been obvious to one of ordinary skills in the art to use acridinium esters as chemiluminescent label as taught by Diamandis in the combined immunoassay method of Petry and Cantor and to detect free PSA because acridinium ester is capable of provide good sensitivity when detecting low amount of sample, i.e. 0.03 ng/mg of total protein.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petry et al. (US 6,406,858) in view of Allard et al. (US 6,107,049) and further in view of Diamandis (5,688,658).

Petry has been discussed above.

However Petry fails to teach specific steps of a sandwich assay for determining total PSA or tPSA.

Allard teaches a two-site immunometric assay method (sandwich method) for determining total PSA or tPSA wherein two anti-PSA antibodies are employed. One of the anti-PSA antibodies is labeled (detection antibody) and the other is immobilized (capture antibody) on a solid phase. The capture and the detection antibodies are contacted simultaneously or sequentially with the test sample. Sequential method can be accomplished by incubating the capture antibody with the sample and adding the detection antibody; the capture antibody is separated from the liquid test mixture, and the label is measured. Label used in the detection antibody can be selected from any of those known conventionally in the art. Commonly, the label is an enzyme or a chemiluminescent moiety, a fluorophor, a radioisotope. The solid phase to which the capture antibody is immobilized can be magnetic particles, latex particles, etc. (see col. 6, line 64-col. 7, line 45.).

It would have been obvious to one of ordinary skills in the art to adapt the teaching of Petry to reduce interferents in the test sample before the performing the assay taught by Allard so that accurate readings and thus accurate test results can be obtained.

Both Petry and Allard fail to teach using acridinium label.

Diamandis teaches using chemiluminescent labels such as acridinium esters in immunoassay to detect prostate specific antigen (PSA). (see col. 5, lines 17-24).

It would have been obvious to one of ordinary skills in the art to use acridinium esters as chemiluminescent label in the immunoassay method taught by Petry and Allard to detect total PSA because acridinium ester is capable of provide good sensitivity when detecting low amount of sample, i.e. 0.03 ng/mg of total protein.

***Maintained Rejection(s)***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Petry et al. (US 6,406,858).

Petry teaches an improvement to the method of determining the concentration of an analyte in body fluid using at least two immunoreactants which specifically bind with separate epitopes of the analyte. The method comprises a step of adding a scavenger conjugate of an enzyme and a water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer to reduce the interaction of the unknown interferents which result in inaccurate readings. The non-proteinaceous polymer is polylysine with molecular weights in the range of from 3 to 250 K Daltons. The specific

binding assay is performed using magnetic particles as solid support. The analytes are Thyroid stimulating hormone, prostate specific antigen, troponin and insulin. (see col. 1, lines 5-10; col. 5, 2, lines 34-65; col. 3, lines 14-36; col. 4, lines 10-18; example 8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petry et al. (US 6,406,858).

Petry has been discussed above.

However, Petry fails to teach detecting free prostate specific antigen.

It would have been obvious to one of ordinary skills in the art to detect free prostate specific antigen since Petry's method can be used to detect prostate specific antigen. Such teaching is broad enough to encompass detection of free prostate specific antigen to one of ordinary skills in the art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petry (US 6,406,858) further in view of Massey et al. (US 5,798,083).

Petry has been discussed above.

However, Petry fails to teach acridinium as chemiluminescent label.

Massey teaches a chemiluminescent TSH immunoassay comprising a monoclonal anti-TSH antibody coated magnetic microparticles; an acridinium ester labeled polyclonal anti-TSH antibody. (See example 11).

It would have been obvious to one of ordinary skills in the art to use acridinium ester as labels as taught in Massey in the method of reducing interferences taught by Petry to detect TSH because acridinium ester is known for its sensitivity with low amount of analytes of interest in a sample. Since the interferences in the sample are also eliminated, acridinium labels would be more sensitive to very low amount of analytes present in the sample. Detection of such low amount of analytes of interest is helpful in the identification of diseases at early stage.

***Response to Arguments***

The arguments filed on June 9, 2003 have been fully considered but not found persuasive.

Regarding the rejection under 35 USC 112, 2nd paragraph, Applicants submit that these rejections have been overcome by amending the claims to include "an assay diluent comprising a large polycation".

This amendment fails to overcome the issue being rejected. The claims were rejected because the preamble recites "A method for decreasing interferences which result in inaccurate readings in serum or plasma sample", but the body of the claims fails to recite any step of decreasing the interferent in serum or plasma. Although the claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the rejections under 35 USC 102 and 103, Applicants traverse the Petry et al. reference that there is nothing in Petry that teaches or suggests to one of ordinary skills in the art that a large polycation that is not conjugated to an enzyme can be used in a specific-binding assay to decrease the interference caused by non-optimal serum or plasma sample preparation techniques, including, but not limited to, inadequate centrifugation, incomplete clotting time, exposure to thermal stresses, etc. Applicants further submit that Petry teaches away from the present invention by teaching that it is only the combination of an enzyme and the water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer that can be used in assays to reduce the interaction of the unknown interferents.

Since the claims of the present invention contain an opening language: "comprising", they fail to exclude any reagents/compounds in addition to the polycation required. Furthermore, the claims fail to recite ***only*** large polycation. Therefore, the references meet the requirement of the present claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
August 18, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641
8/21/03